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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/757,646

01/13/2004

Tracee Eidenschink

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CROMPTON, SEAGER & TUFTE, LLC  
1221 NICOLLET AVENUE  
SUITE 800  
MINNEAPOLIS, MN 55403-2420

EXAMINER

SEVERSON, RYAN J

ART UNIT

PAPER NUMBER

3731

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/757,646	<b>Applicant(s)</b> EIDENSCHINK ET AL.	
	<b>Examiner</b> Ryan J. Severson	<b>Art Unit</b> 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 06 January 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-9, 15, 21, 22, 24-38, 51-62 and 65-67 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 15, 21, 22, 24-38, 51-62 and 65-67 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claim 62 is rejected under 35 U.S.C. 102(b) as being anticipated by Alba et al. (5,634,901).** Alba et al. disclose a catheter assembly comprising a catheter shaft (10) having a balloon (12) mounted on the shaft, the balloon having tapered proximal and distal ends (see figures 1A-1C). The assembly further includes a sheath (18) disposed about the balloon, where the sheath has tapered ends (as in figure 1C) that align with the tapered ends of the balloon to prevent longitudinal displacement of the balloon relative to the sheath. Examiner further takes the position that the sheath is capable of rotating relative to the balloon.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. **Claims 1, 2, 5-9 and 31-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox (5,257,974).** Cox discloses a catheter assembly with a balloon catheter (see figure 22) disposed within a rotatable sheath (350). The rotatable sheath

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has a guidewire housing (the guidewire can pass through any of the bores 368). The structure that defines the bores (i.e. the dividers 366 and the cylindrical sheath wall) is considered engaged to the outer surface of the sheath, since it is connected and part of the outer surface of the sheath). However, the embodiment shown in figure 22 does not have end portions of the sheath that have a smaller inner diameter than the central portion. Attention is drawn to figure 8 of Cox, which shows a tubular member having a tapered end to present a less traumatic end to the hollow member that enhances the safe advancement of the tubular member in a vessel (see column 9, lines 20-29). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the ends of the sheath (350 shown in figure 22 of Cox) with tapered ends as in figure 8 to present atraumatic ends of the sheath for insertion and retraction in the blood vessel.

5. Regarding claims 31-38, Cox does not disclose the materials for the sheath as claimed. It would have been obvious to one having ordinary skill in the art to make the sheath of the claimed materials, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

6. **Claims 3, 4, 15, 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox (5,257,974 as applied to claim 1 above, and further in view of Wilson et al. (6,165,195).** Cox does not disclose a stent disposed about the sheath and guidewire housing. Attention is drawn to Wilson et al., who teach the use of a stent disposed about a guidewire assembly (see figure 13D) and balloon to allow the stent to

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be placed at a point of a bifurcation. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have disposed a stent about the guidewire housing and sheath of Cox in the manner taught by Wilson et al. to allow the balloon catheter to deliver a stent to a point of a vessel bifurcation.

7. **Claims 24-29 and 51-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox (5,257,974) and Wilson et al. (6,165,195) as applied to claim 15 above, and further in view of Healy et al. (5,670,161).** The combination of Cox and Wilson et al. does not disclose the stent has therapeutic coatings disposed thereon. Attention is drawn to Healy et al., who teach the use of various therapeutic coatings on a stent to speed healing at the site of deployment of the stent. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included a therapeutic coating on the stent of the combination of Cox and Wilson et al. in the manner taught by Healy et al. to speed healing at the site of deployment of the stent.

8. **Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cox (5,257,974) as applied to claim 1 above, and further in view of Lenker et al. (6,350,278).** Cox does not disclose a lubricious coating positioned between the sheath and the shaft. Attention is drawn to Lenker et al., who teach a lubricious material applied between the catheter shaft and the sheath (see Column 9, Lines 58-64) to reduce the amount of friction between the two components. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a lubricous coating between the sheath and the catheter shaft in the manner

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taught by Lenker et al. in the device of Cox to reduce the amount of friction between the two components.

9. **Claim 65 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alba et al. (5,634,901) in view of Wilson et al. (6,165,195).** Alba et al. do not disclose a stent disposed about the sheath and guidewire housing. Attention is drawn to Wilson et al., who teach the use of a stent disposed about a guidewire assembly (see figure 13D) and balloon to allow the stent to be placed at a point of a bifurcation. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have disposed a stent about the guidewire housing and sheath of Alba et al. in the manner taught by Wilson et al. to allow the balloon catheter to deliver a stent to a point of a vessel bifurcation.

10. **Claim 66 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alba et al. (5,634,901) in view of Cox (5,257,974).** Alba et al. fail to disclose a guidewire housing engaged to an outer surface of the sheath. Attention is drawn to Cox, which teaches a housing (32, see figures 18 and 19) engaged to an outer surface of the sheath (302) to allow blood to pass the balloon to prevent total occlusion. Examiner notes that the housing (32) is capable of receiving a guidewire. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have added a housing on the sheath of Alba et al. in the manner taught by Cox to allow blood to pass the balloon to prevent total occlusion. The combined device would allow a guidewire to pass through the housing.

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11. Examiner further notes that the fact that applicant has recognized another advantage (i.e. allowing a guidewire to pass through the housing) which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

12. **Claim 67 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alba et al. (5,634,901).** Alba et al. fail to disclose the materials and hardnesses as claimed. It would have been obvious to one having ordinary skill in the art to make the sheath of the claimed materials, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

### ***Response to Arguments***

13. Applicant's arguments filed 1/6/2010 have been fully considered but they are not persuasive.

14. First, regarding claim 62, applicant argues Alba et al. fail to disclose the new limitation requiring the first and second tapered ends of the sheath and balloon are configured to complement one another to longitudinally secure the rotatable sheath relative to the balloon. However, Examiner takes the position that this limitation is met when the balloon is in the expanded state (as in figure 1C of Alba et al.). Examiner suggests amending this claim to clarify that the sheath and balloon are longitudinally secured relative to one another when the balloon is in both the expanded and deflated

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(or unexpanded) state. Such an amendment would be effective to define over the Alba et al. disclosure.

15. Regarding claim 1, applicant argues one having ordinary skill in the art wouldn't modify the embodiment of figure 22 with a tapered end as shown in figure 8 of Cox. However, Examiner asserts that making the distal end a cylindrical structure tapered to allow it to pass easier through the vasculature is advantageous, regardless of whether the sheath is disposed around the balloon (as in figure 22) or adjacent the balloon (as in figure 8). Examiner notes that the modification does not suggest tapering the end of the sheath to such an extent that would prevent it from passing over the unexpanded balloon.

16. Further regarding claim 1, the "outer surface" of the sheath does not need to be the radially outer surface, but could also be considered the planar distal surface, and the structure suggested as defining the guidewire housing is at least engaged to that outer surface.

17. Examiner suggests amending claim 1 to clarify that the balloon and sheath are fixed relative to one another in the same manner as claimed in claim 62 to define over Cox.

### ***Conclusion***

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).



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19. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ryan J. Severson whose telephone number is (571) 272-3142. The examiner can normally be reached on Monday - Friday 8:30-5:00.

21. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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22. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ryan J. Severson/  
Examiner, Art Unit 3731  
2/24/10

/Anhtuan T. Nguyen/  
Supervisory Patent Examiner, Art Unit 3731  
3/1/10